OCT 0 2 2002

Exhibit IV: 510(k) Summary

K022953

Schick Computed Oral Radiology System

Common/Classification Name: Solid State X-ray Imager
21 CFR892.1650

Schick Technologies, Inc.
30-00 47th Avenue
Long Island City, NY 11101
718-937-5765, 718-937-5962 (FAX)
Contact: Daniel Michaeli, Prepared: September 4, 2002

A. Legally Marketed Predicate Devices

The original Computed Oral Radiology System notification was cleared on January 31st, 1994 (K933455). The device and its predicate are small digital imaging receptors that may be used in place of dental x-ray film.

B. Modification Description

The proposed device modification alters the method of communication between the sensor and computer from a wired to wireless interface. Thus, there is an introduction of a new energy type, a radio frequency transmitter. In this mode, the wireless sensor is powered via a battery rather than a DC-supply derived from AC mains voltage.

The operating principle differs in that image acquisition is mediated through hardware rather than software components. Whereas software in the predicate device "polled" the sensor to investigate whether acquisition had commenced, the modified device utilizes a hardware component. This modification is necessary to reduce the sensor's idle state power to a minimum.

To facilitate RF transmission, the sensor encapsulation material has been modified from aluminum to a thermoplastic resin. Thermoplastic resins are utilized in other FDA-approved dental sensors. The specific thermoplastic resin chosen for this application has been approved for incidental food contact. The duration and nature of body contact with materials in that discipline is greater than what a patient would endure with a sheath encapsulated sensor.

The existing firmware has been altered to support the modified and additional hardware. Whereas the predicate device had firmware installed on the Remote module, the new device has firmware installed both on the remote module and

on the sensor. The firmware on the sensor facilitates unidirectional communication of image and sensor status data to the remote module.

C. Indications for Use

The Computed Oral Radiology System is indicated for patients undergoing an intra-oral dental x-ray examination. It produces instant, digital, intra-oral x-ray images of a patient's mouth while reducing the necessary x-ray dosage. This device modification in no way alters the indications for use of this machine beyond what was originally approved in K933455.

D. Substantial Equivalence Summary

The intended use of the **Computed Oral Radiology System** remains unchanged. The new product transmits data through a wireless rather than wired interface to the host image processing system. This and the concomitant modifications in no way alter the fundamental scientific technology governing image acquisition. Those imaging parameters that could be potentially affected by the modification as are outlined generally in the document, "Guidance for the Submission of 510(k)'s for Solid State X-ray Imaging Devices" were found to be substantially equivalent to the predicate.

E. Technological Characteristics

Part B of this section describes the technological characteristics of the modified device. The technological characteristics of this machine have been examined through a risk analysis. The fundamental technology remains unchanged from the predicate.

F. Risk Analysis and Validation study

As a result of risk analysis activities performed in conformance with our ISO9001 quality program along with supporting bench-lab measurements, Schick Technologies has determined the effect of the proposed changes to be negligible.

G. Conclusions

Schick Technologies has demonstrated through a risk analysis and validation studies that the device modification is substantially equivalent to the already cleared and marketed device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 02 2002

Daniel Michaeli, M.S.
Product Manager
Schick Technologies, Inc.
30-00 47th Avenue
LONG ISLAND CITY NY 11101

Re: K022953
Trade/Device Name: Computed Oral Radiology System
Regulation Number: 21 CFR §892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Product Code: 90 MQB
Regulation Number: 21 CFR §872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: II
Product Code: 90 MUH
Dated: September 3, 2002
Received: September 5, 2002

Dear Mr. Michaeli:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Exhibit III: Indications for Use

510(k) Number (if known): K022953

Device Name: Computed Oral Radiology System

Indications For Use:

The Computed Oral Radiology System is indicated for patients undergoing an intra-oral dental x-ray examination. It produces instant, digital, intra-oral x-ray images of a patient's mouth while reducing the necessary x-ray dosage.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

Prescription Use ✓

David A. Seguin

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K022953